CLAIM OBJECTIONS

The Examiner has stated that Claim 31 is objected to because of the following informalities: Claim 3, lines 2-9, recite "said cylindrically shaped expansion member mesh, previously in line 7 Applicant claims "a cylindrically shaped expansion member". The Examiner can not ascertain whether Applicant intended to further limit the structure to a "mesh", or merely made a mistake in the Amendment submitted on 12 December 2003 by failing to delete "mesh" from the body of the claim.

The Examiner has required appropriate correction.

Response:

The Applicant has amended Claim 31 and deleted the word "mesh" from the claim. Applicant now believes that the objection has been overcome.

The Examiner also stated that Claim 32 is objected to because of the following informalities: Claim 32, line 4, recites "a predetermined side". The Examiner believes it was Applicant's intent to recite "a predetermined site".

The Examiner has required appropriate correction.

Response:

The Examiner is correct in the it was the Applicant's intent to recite "a predetermined site". Appropriate corrections have been made in Claim 32.

CLAIM REJECTIONS -35 USC § 102

The Examiner stated that claims 31, 32, 34, 35, 37, 38, 46, 47, 53, 61, 64-68, 74, 82 and 85-88 are rejected under 35 U.S.C. 102(a) or (C) as being anticipated by Brown III et al. (US 6,219,577 BI).

In making this conclusion, the Examiner stated that Brown III et al. discloses an iontophoresis, electroporation and combination catheter for local drug delivery to arteries and other body tissues, comprising, a catheter (10) having a distal end (14), a proximal end (12), and an iontophoretic transport means (24), the catheter having one lumen (see Figure 3) or more lumens (see Figure 4); a cylindrically shaped expansion member (20) coated or impregnated with a drug or other therapeutic agent positioned on the distal end of the catheter, the cylindrically shaped expansion member having a first contracted diameter (see Figure 1) and a second expanded diameter (see Figure 2), the second expanded diameter being larger than the first contracted diameter; see Column 8, lines 13-27, Column 9, lines 1-26; Column 10, lines 13-17 and lines 35-68; Column II, lines 22-63; Column 14, lines 17-68 and Column 13, lines 1-22 and lines 62-63.

Response:

The Brown III et al. patent discloses several embodiments of catheter designs to be used for the prevention of restenosis following angioplasty in arteries and treatment of other organs using iontophoresis and electroporation. One embodiment that is the most relevant to the Applicant's present invention comprises a catheter with a distal end composed of flexible individual wire electrodes (expandable tubular braided sleeve, column 9, lines 4-5) which are mounted around and parallel to the longitudinal axis of the catheter body (column 9, lines 5-6). When located in the body, the electrodes (24) can be mechanically expanded and the middle region of the expanded electrodes is closely

juxtaposed to the tissue to be treated (column 9, lines 16-19). Only the middle region of the electrodes is coated with a visco-elastic polymer matrix incorporating drug or other therapeutic agents (column 9, lines 20-22). The electrodes may be alternated with polyester monofilaments, also in a parallel arrangement to the catheter body, to provide structural support (column 9, lines 44-46).

The catheter of the above invention may be used after the sequence of balloon dilatation (separate device) that has been completed and the dilatation balloon is withdrawn (column 6, lines 24-26). Alternatively, the Brown III et al. catheter may be used before balloon dilatation (column 6, lines 33-36).

In another embodiment of the catheter, the polymer matrix containing the drug may be molded into a short tubular expandable visco-elastic sleeve which fits over the middle region of the electrode array.

There are several physical and functional features of the Applicant's present invention which distinguish it from the Brown III et al. disclosure. These physical and functional features of the Applicant's present invention also provide clinical applications and significant advantages that are neither claimed nor disclosed in the Brown III et al. patent. Furthermore, the Applicants respectfully disagree with the Examiner in that the Brown III et al. device does not disclose or claim the Applicants' cylindrically shaped expansion member.

The electrodes of the Brown III et al. invention are oriented "parallel to the catheter body". This is an essential feature of the Brown III et al. invention for it is what allows "the electrodes to lie substantially flat when the electrodes are in a relaxed position" (Brown III et al. Claim 1, lines 31-32). The distal wire mesh of the Applicant's present invention is a circumferentially braided wire mesh which is not oriented parallel to the

catheter body. In addition, the Applicant's wire mesh does not lie substantially flat against the catheter body when in a relaxed position.

In addition, the distal end of Brown III et al. device comprises an arcuate shape when the electrodes are in an expanded configuration. In contrast, when expanded, the distal wire mesh of the Applicant's present invention does not have a series of arcuate shaped electrodes but rather comprises a cylindrically shaped expansion member. Upon expansion of the Brown III et al. electrodes, only the middle portions of the wire elements contact the tissue. This is due to the arcuate nature of the electrodes which are parallel to the catheter body. In the Applicants' present invention, the distal wire mesh electrode is cylindrically shaped (as disclosed and claimed) to provide maximum tissue contact along the entire length of the cylindrically shaped expansion member upon expansion. Furthermore, the polymer coating of the electrodes of the Brown III et al. invention are only in the middle sections of the electrodes because this is the section that contacts the vessel walls. The entire cylindrical dilating member of the Applicants' invention is coated with a drug or drug containing polymer to maximize the contact surface and delivery area. This is important clinically since treatment sites, such as in the coronary vessels, are commonly at least 10 to 15 mm in length. The Applicants' present invention is designed to have the capability to treat the entire length of such lesions in a single application. Conversely, the Brown III et al. invention is limited to providing treatment in the middle portion of his device. Therefore, a relatively smaller area (approximately 2 to 3 mm in length) is treated with each expansion of the Brown III et al. device. Since the therapeutic dose is now delivered and thus exhausted, the Brown III et al. device must be retracted and a new Brown III et al. device advanced to the lesion. Hence, the Applicant asserts that there are a number of significant clinical disadvantages to the Brown III et al. device. In the case of the coronary 15 mm lesion, as many a 4 or 5 Brown devices may be needed to treat this lesion while the cylindrically shaped expansion member of the Applicant's invention is typically 10 to 15 mm in length and therefore can treat the full length of these

lesions in one application. The design characteristics of Brown III et al. invention is further complicated in that it is not always possible to re-gain access to a treatment site once the original interventional device has been retracted. Furthermore, there is an increased risk of immediate complications or subsequent medical consequences when multiple interventional devices are advanced through the patient's vasculature.

Additionally, the Brown III et al. invention discloses that is to be used either following, or prior to, a balloon angioplasty procedure. The design of the Brown III et al. distal electrodes do not have the capability of generating the radial forces necessary to dilate the blood vessel or organ. As disclosed and claimed in the present invention application, the circumferentially oriented wire braid of the Applicant's invention is designed to generate sufficient radial forces upon expansion to dilate or further enhance a previously dilated diseased segment in a blood vessel. The Brown III et al. device may require a dilatation balloon or other clinical device to gain access to the diseased vessel. Furthermore, once in position and if additionally dilatation is required, the Brown III et al. device must be retracted for another angioplasty balloon or device to gain access and treat the diseased segment.

Thus, Applicants respectfully submit that claims 31, 32, 34, 35, 37, 38, 46, 47, 53, 61, 64-68, 74, 82 and 85-88 are patentably distinct and are fully distinguishable over Brown III et al. Withdrawal of this 102(b) rejection is therefore requested.

CLAIM REJECTIONS -35 USC § 103

The Examiner has rejected Claims 33 and 36 under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577 BI) in view of Gencheff et al. (US 5,423,744 A).

In making this conclusion, the Examiner stated that Brown, III et al. discloses the invention as claimed with the exception of the method step of positioning a guidewire in the body passageway, and wherein the advancing step is accomplished by threading the expansion member over the guidewire, Gencheff et al. disclose a catheter system for the deployment of biological material, as shown in Figures 7-10, comprising the method step of positioning a guidewire in the body passageway, and wherein the advancing step is accomplished by threading the expansion member over the guidewire, see Column 10, line 60 through Column II, line 20.

The Examiner stated that it would have been obvious to one having ordinary skill in the art to have modified Brown, III et al.'s disclosed method of use with the added steps of positioning a guidewire in the body passageway, and threading the expansion member over the guidewire, so as to more effectively control placement of the device at the treatment site.

Response:

First, Applicant is incorporating by reference the arguments made above (Claim Rejection- 35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

Gencheff et al. employs a dual balloon catheter with an intermediate treatment area for electrical input capable of time-variable modulation of a charge applied by the electrode means. The Applicant's present invention does not have any balloons, rather it utilizes a single expandable mesh or member which has perfusion capabilities for prolonged dilatation and exposure. Furthermore, the expandable mesh or member does not have the balloon puncture disadvantage that is inherit in balloon technology.

In addition, the electrodes of the Gencheff et al. device is designed like the Brown III et al. invention, both which are oriented "parallel to the catheter body". The distal wire mesh of Applicant's present invention is a circumferentially braided wire mesh which is not oriented parallel to the catheter body. Furthermore, when expanded, the distal wire mesh of the Applicant's present invention does not have a series of arcuate shaped electrodes but rather comprises a cylindrically shaped expansion member. Upon expansion of the electrodes of the Gencheff et al. invention, only the middle portions of the wire elements contact the tissue (See Figure 10). This is due to the arcuate nature of the electrodes which are parallel to the catheter body.

Furthermore, in the Applicant's present invention, the distal wire mesh electrode is cylindrically shaped (as disclosed and claimed) to provide maximum tissue contact along the entire length of the cylindrically shaped expansion member upon expansion. Coating of the electrodes of the Gencheff invention are only coated in the middle sections of the electrodes. Because of the arcuate shape of the "conductors" is only the middle section that contacts the vessel walls. The entire cylindrical dilating member of the Applicants' invention is coated with drug (or drug polymer) in order to maximize the contact surface and delivery area.

In addition, one the primary element of establishing a prima facie case of obviousness is that the references require some reason, suggestion, or motivation from the

prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to this required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." (See *In re* Geiger, 815 F.2d 686, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987). *See also* Diversitech Corp. v. Centure Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ 2d 1315, 1318 (Fed. Cir. 1988); W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303, 311 (Fed. Cir. 1983):

The Applicant respectfully asserts that there is no teaching, motivation, or incentive motivation in either the Brown III et al. patent or Gencheff et al. that supports the combining of the two prior art references as required by current patent law.

Reconsideration is requested of the rejection of claims 33 and 36 as being patentable under 35 U.S.C. '103 in view of the disclosures of the Brown III et al. and Gencheff et al. patent. Furthermore, the Brown III et al. and the Gencheff et al. patent fail to suggest those features of Applicants' invention, as discussed above. Appropriate withdrawal of this 103(a) rejection is therefore requested.

<u>CLAIM REJECTIONS -35 USC § 103</u>

The Examiner has rejected Claim 45 under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al.(US 6,219,377 B1) in view of Dubrul et al. (US 6,450,989 A).

The Examiner stated that Brown III et al, discloses the invention as claimed with the exception of the cylindrically shaped expansion member comprising a first plurality of flexible elongate elements helically wound in a first direction or rotation and a second

plurality of flexible elongate elements helically wound in a second direction of rotation to form a braid.

The Examiner stated that Dubrul et al. discloses a dilating and support apparatus comprising a dilation mechanism (9), as depicted in Figures 4-A and 4-B, made of an open, mesh metal braid, which allows for perfusion therethrough and is formed by a "Maypole" dance of filament carriers to create a zigzag pattern, wherein one filament moves helically clockwise and the other moves helically counter-clockwise, see Column 13, line 35 through Column 14, line 28; Column 17, lines 30-31; and Column 21, line 4 through Column 22, line 55.

The Examiner concluded that it would have been obvious to one having ordinary skill in the art to have modified Brown, III et al.'s cylindrically shaped expansion member with an open, mesh braid as taught by Dubual et al. so as to increase the amount of surface area of the device in contact with the vessel wall thereby enabling more controlled and accurate delivery of medicament to affected wall tissue.

<u>Response:</u>

Applicant is incorporating by reference the arguments made above (Claim Rejection- 35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

Applicant contends that the Dubrul et al. discloses a woven mesh made of absorbent braid material for contact drug delivery (9, 62). Dilatation is performed only by placing the absorbent braid "over an angioplasty balloon (9, 45). Such absorbent braid materials would not be capable of generating sufficient force to dilate a stenosis in a blood vessel.

The Applicants' present invention utilizes a specifically designed mesh for dilatation and drug delivery and does not employ an angioplasty balloon.

Alternatively the Dubrul braid may be constructed of tiny tubular filaments with means for injecting fluid into the filaments (10, 17). There is no mention in Dubrul of coating the filaments of the absorbent braid with any type of polymeric coating containing the drugs to be delivered by contact with the vessel wall. There is no cylindrical dilating element disclosed capable of dilating a blood vessel and acting as an electrode of increased surface area for presentation of increased amounts of drug and electrical energy to the vessel wall. The Dubrul braid is not used as an electrode itself and is noted to possibly "contain an internal electrode" (18, 7-9).

There is no suggestion that combining the absorbent braid of the Dubrul device with the arcuate electrodes of the Brown III et al. device will result in the Applicants' current invention.

The Applicant respectfully asserts that there is no teaching, motivation, or incentive motivation in either the Brown III et al. patent or Dubrul et al. that supports the combining of the two prior art references as required by current patent law.

Reconsideration is requested of the rejection of claim 45 as being patentable under 35 U.S.C. '103 in view of the disclosures of the Brown III et al. and Dubrul et al. patent. Furthermore, the Brown III et al. and the Debrul et al. patent fail to suggest those features of Applicants' invention, as discussed above.

CLAIM REJECTIONS -35 USC § 103

The Examiner stated that Claims 48, 49, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577 Bl) in view of Segal (US 5,527,282 A).

The Examiner stated that Brown, III et al. discloses the invention as claimed with the exception an anticoagulant, such as heparin or the like.

The Examiner stated that Segal discloses a vascular dilatation device for localized delivery of heparin, TPA, hirudin or various anti-thrombin agents, see Column 10, lines 55-61.

The Examiner concluded that it would have been obvious to one having ordinary skill in the art to have modified Brown. III et al. s catheter for local drug delivery with heparin delivery as taught by Segal, so as to prevent clotting of the blood adjacent the dilation device.

Response:

Applicant is incorporating by reference the arguments made above (Claim Rejection- 35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

Segal discloses a vascular dilatation device which uses injection of drugs via a catheter lumen in the vicinity of the distal dilating mesh. There is no suggestion or teaching in the Segal disclosure of incorporating the drug into a coating on the dilating mesh in order to contact the vessel wall for delivery. There is also no mention of using iontophoresis or electrical energy to augment drug delivery.

There is no suggestion to combine the injection of drugs in the area of dilatation with the Brown III et al. device using arcuate electrodes coated with drug only in the middle section of the arcuate electrodes.

The Applicant respectfully asserts that there is no teaching, motivation, or incentive motivation in either the Brown III et al. patent or Segal that supports the combining of the two prior art references as required by current patent law.

Reconsideration is requested of the rejection of claims 48, 49, 69 and 70 as being patentable under 35 U.S.C. '103 in view of the disclosures of the Brown III et al. and Segal patent. Furthermore, the Brown III et al. and the Segal patent fail to suggest those features of Applicants' invention, as discussed above. Appropriate withdrawal of this 103(a) rejection is therefore requested.

CLAIM REJECTIONS -35 USC § 103

The Examiner stated Claims 48, 49, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. in view of Tsugita (US 6,142,987 A).

The Examiner stated that Brown, III et al. discloses the invention as claimed with the exception an anticoagulant, such as heparin or the like.

The Examiner stated that Tsugita discloses an endovascular filter device coated with heparin and heparinoids (see Columns, lines 31-33).

The Examiner concluded that it would have been obvious to one having ordinary skill in the art to have modified Brown, Ill et al.'s cylindrically shaped expansion member

"with a hepathil heparinoid coating" as taught by Tsugita, so as to reduce thrombi formation of the flexible elongate elements which comprise the expansion member thus ensuring adequate sustained perfusion there through.

Response:

Applicant is incorporating by reference the arguments made above (Claim Rejection- 35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

Tsugita discloses an endovascular filter coated with heparin to reduce thrombi formation on the mesh (5, 32-33). The Applicant asserts that the device disclosed is not a cylindrical mesh structure with dilating capabilities, nor can it be used for drug delivery to the vessel wall.

Furthermore, there is no teaching to suggest combining this device with the arcuate electrodes of the Brown '577 patent to enhance drug delivery or perform iontophoresis.

The Applicant respectfully asserts that there is no teaching, motivation, or incentive motivation in either the Brown III et al. patent or Tsugita that supports the combining of the two prior art references as required by current patent law.

Reconsideration is requested of the rejection of claims 48, 49, 69 and 70 as being patentable under 35 U.S.C. '103 in view of the disclosures of the Brown III et al. and Tsugita patent. Furthermore, the Brown III et al. and the Tsugita patent fail to suggest those features of Applicants' invention, as discussed above. Appropriate withdrawal of this 103(a) rejection is therefore requested.

CLAIM REJECTIONS -35 USC § 103

The Examiner stated that Claims 50-52, 54-58, 62, 63, 71-79, 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577 BI) in view of Lennox (US 6,280,411 BI), Palasis et al. (US 6,369,039 BI), or Naimark et al. (US 6,638,246 B1).

The Examiner stated that Brown. III et al. discloses the invention as claimed with the exception of Applicant's claimed medicament groups as outlined in Applicant's Claims 50-52, 54-58, 62. 63, 71-79, 83 and 84.

The Examiner stated that Lennox (Column 4, line 22 through Column 5, line 35), Palasis et al. (Column 4, line 64 though Column 6, line 22), and Naimark et al. (Column 8, line 50 through Column 10, line 23), all individually, discloses a device for localized delivery of drug agents comprising an expansion member (210, 120, l0/20A/20B/30/40A/ 40B/50/60/80A/80B, respectively) coated with a medicament comprising a promoter of vascular cell growth, a transcriptional activator, an inhibitor of vascular cell growth, a growth factor receptor antagonist, a cholesterol-lowering agents, a vasodilating agent, an agent that interferes with endogenous vasoactive mechanisms, estrogen, a smooth muscle inhibitor, a compound that inhibits cellular proliferation, and paclitaxel.

The Examiner concluded that it would have been obvious to one having ordinary skill in the art to have modified Brown, Ill et al.'s cylindrically shaped expansion member with a variety of drugs as taught by Lennox, Palasis et al. or Naimark et al., so as to enable treatment of a variety of conditions including localized disease and/or vessel occlusion.

Response:

Applicant is incorporating by reference the arguments made above (Claim Rejection- 35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

Lennox discloses an elastic sheath which emits drugs when expanded by a balloon catheter. There is no disclosure or suggestion of a cylindrical mechanical dilatation mesh catheter. Furthermore, there is no disclosure or suggestion of a means of active transport of drug or therapeutic agent via iontophoresis or electroporation. The elastic sheath is intended to be used with an angioplasty balloon and is incapable itself of dilating a stenosis in a manner similar to the Applicant's claimed invention.

There is no teaching to combine the drug delivery sheath of Lennox with the arcuate electrode catheter of Brown III et al.

The Applicant respectfully asserts that there is no teaching, motivation, or incentive motivation in either the Brown III et al. patent or Lennox that supports the combining of the two prior art references as required by current patent law.

Reconsideration is requested of the rejection of claims 50-52, 54-58, 62, 63, 71-79, 83 and 84 as being patentable under 35 U.S.C. '103 in view of the disclosures of the Brown III et al. and Lennox patent. Furthermore, the Brown III et al. and the Lennox patent fail to suggest those features of Applicants' invention, as discussed above. Appropriate withdrawal of this 103(a) rejection is therefore requested.

Naimark discloses a balloon catheter with micro-needles for local drug delivery.

There is no disclosure or suggestion of a cylindrical mechanical dilating mesh capable of drug delivery to the vessel wall.

Again, there is no teaching or suggestion to combine the drug delivery balloon of Naimark with the arcuate electrode catheter of Brown III et al.

The Applicant respectfully asserts that there is no teaching, motivation, or incentive motivation in either the Brown III et al. patent or Naimark et al. that supports the combining of the two prior art references as required by current patent law.

Reconsideration is requested of the rejection of claims 50-52, 54-58, 62, 63, 71-79, 83 and 84 as being patentable under 35 U.S.C. '103 in view of the disclosures of the Brown III et al. and Naimark et al. patent. Furthermore, the Brown III et al. and the Naimark et al. patent fail to suggest those features of Applicants' invention, as discussed above. Appropriate withdrawal of this 103(a) rejection is therefore requested.

Palasis discloses a drug delivery catheter which delivery therapeutic agents by local injection and may be used with an angioplasty balloon. There is no disclosure or suggestion of a cylindrical mechanical dilatation mesh catheter. Furthermore, there is no disclosure or suggestion of a means of active transport of drug via iontophoresis or electroporation.

Again, there is no teaching or suggestion to combine the drug delivery injection catheter of Palasis et al. with the arcuate electrode catheter of Brown III et al.

The Applicant respectfully asserts that there is no teaching, motivation, or incentive motivation in either the Brown III et al. patent or Palasis et al. that supports the combining of the two prior art references as required by current patent law.

Reconsideration is requested of the rejection of claims 50-52, 54-58, 62, 63, 71-79, 83 and 84 as being patentable under 35 U.S.C. '103 in view of the disclosures of the Brown III et al. and Palasis et al. patent. Furthermore, the Brown III et al. and the Palasis et al. patent fail to suggest those features of Applicants' invention, as discussed above. Appropriate withdrawal of this 103(a) rejection is therefore requested.

CLAIM REJECTIONS -35 USC § 103

The Examiner stated that Claims 59, 60, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577 BI) in view of Hanson et al. (US 985,307A),

The Examiner stated that Brown, III et al. discloses the invention as claimed with the exception of Applicant's claimed medicament groups as outlined in Applicant's Claims 59, 60, 80 and 81.

The Examiner stated that Hanson et al. (Column 18, line 50 through Column 19, line 33; and Column 26, line 62 through Column 27, line 3) discloses a device for localized delivery of drug agents comprising an expansion member (50) containing a medicament comprising an agent that modulates intracellular calcium binding proteins and a receptor blocker for contractile agonists.

The Examiner concluded that it would have been obvious to one having ordinary skill in the art to have modified Brown, III et al.'s cylindrically shaped expansion member with a variety of drugs as taught by Hanson et al. so as to enable treatment of a variety of conditions including localized disease and/or vessel occlusion.

Response:

Applicant is incorporating by reference the arguments made above (Claim Rejection- 35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

Hanson discloses an inflatable balloon catheter with drug delivery means. There is no disclosure or suggestion of a cylindrical mechanical dilatation mesh catheter. Furthermore, there is disclosure or suggestion of a means of active transport of drug via iontophoresis or electroporation.

There is no teaching or suggestion to combine the drug delivery injection catheter of Hanson with the arcuate electrode catheter of Brown III et al. in order to enhance drug delivery.

The Applicant respectfully asserts that there is no teaching, motivation, or incentive motivation in either the Brown III et al. patent or Hanson et al. that supports the combining of the two prior art references as required by current patent law.

Reconsideration is requested of the rejection of claims 50-52, 54-58, 62, 63, 71-79, 83 and 84 as being patentable under 35 U.S.C. '103 in view of the disclosures of the Brown III et al. and Hanson et al. patent. Furthermore, the Brown III et al. and the Hanson et al. patent fail to suggest those features of Applicants' invention, as discussed above. Appropriate withdrawal of this 103(a) rejection is therefore requested.

ALLOWABLE SUBJECT MATTER

The Examiner stated that Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

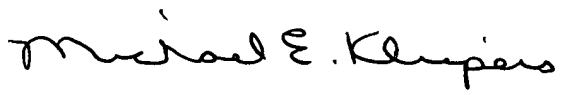
Response:

The Applicant has amended Claim 39 to include the limitations of the base claim and any intervening claims. Applicant believes amended claim 39 is now allowable.

The Applicants have amended the specification and claims according to the comments made by the Examiner. Furthermore, the Applicants have enclosed amended drawing sheets and marked-up drawing sheets. No new matter is or has been added.

Based on the foregoing, Applicant respectfully submits that the application now is in condition for allowance. If any matters can be resolved by telephone, the Examiner is invited to call the undersigned attorney at the telephone number listed below.

Respectfully submitted,



Michael E. Klicpera, Esq., Reg. No. 38,044

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La Jolla, California 92038-0573
Telephone: (619) 980-8680

EXHIBIT A

DRAWING SHEETS

FIG. 1

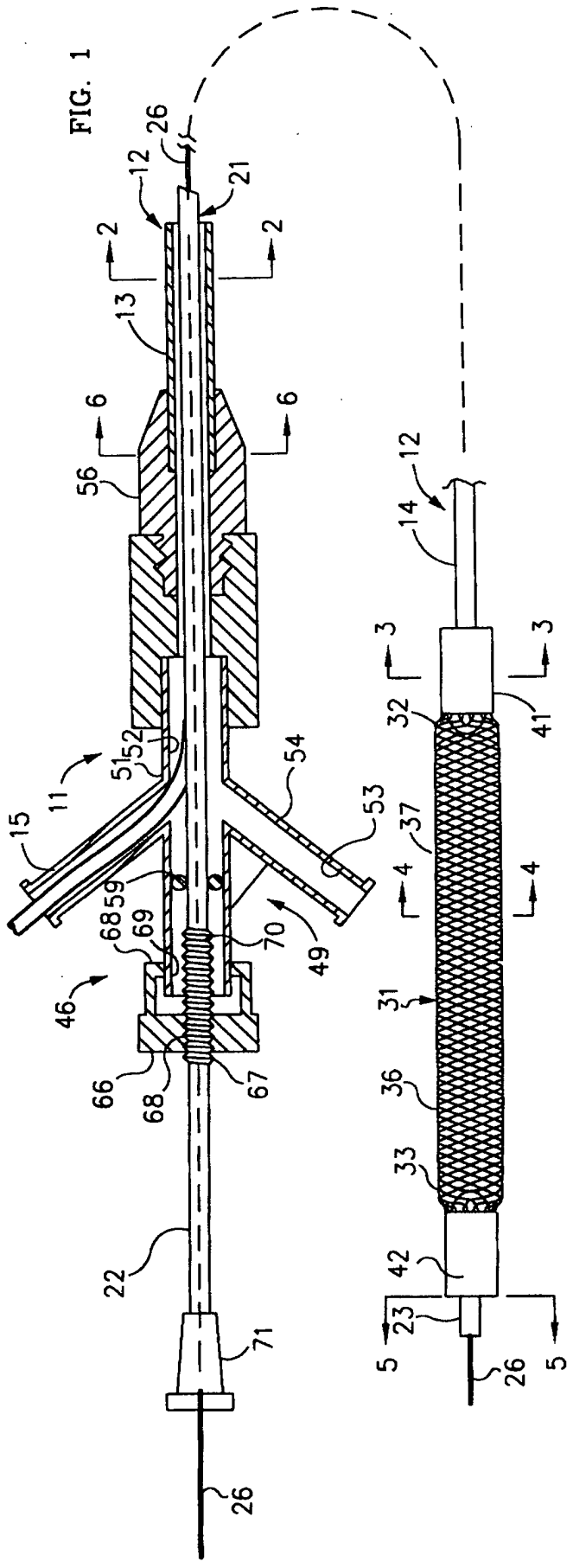


FIG. 2

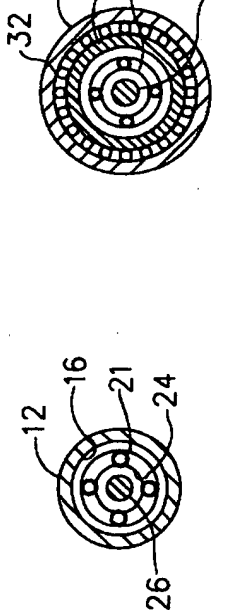


FIG. 3

FIG. 4

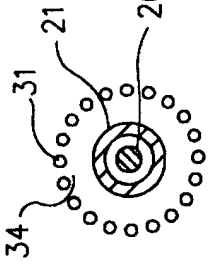


FIG. 5

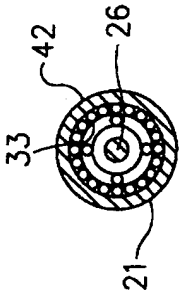


FIG. 6

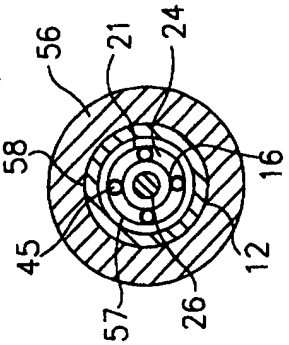


FIG. 7

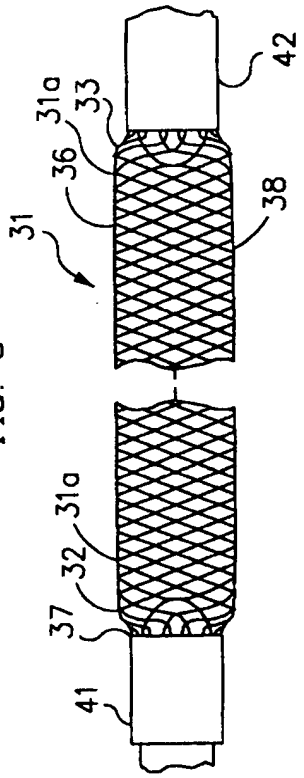


FIG. 8A

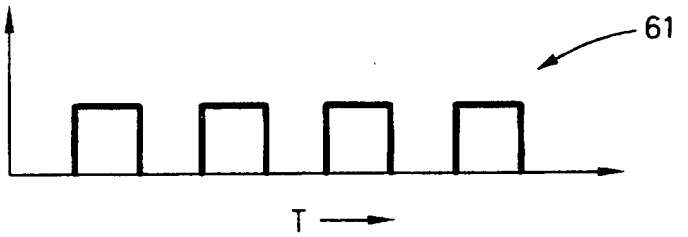


FIG. 8B

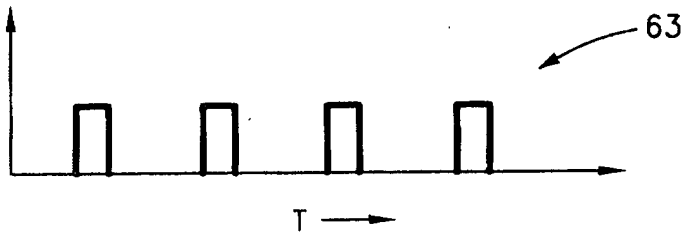


FIG. 8C

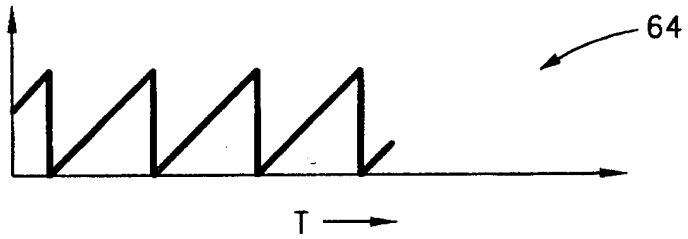


FIG. 8D

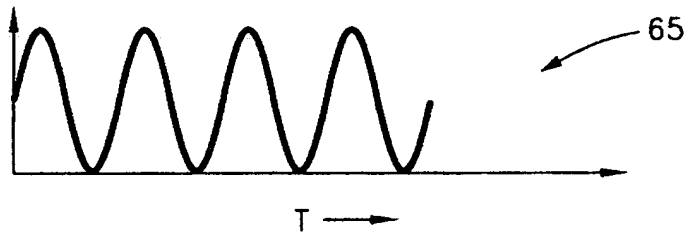


FIG. 8E

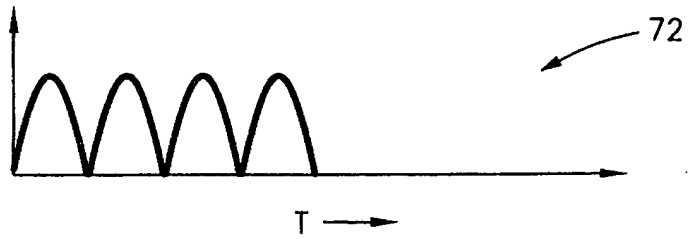
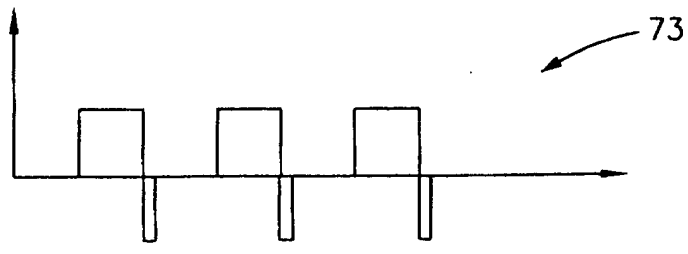


FIG. 8F



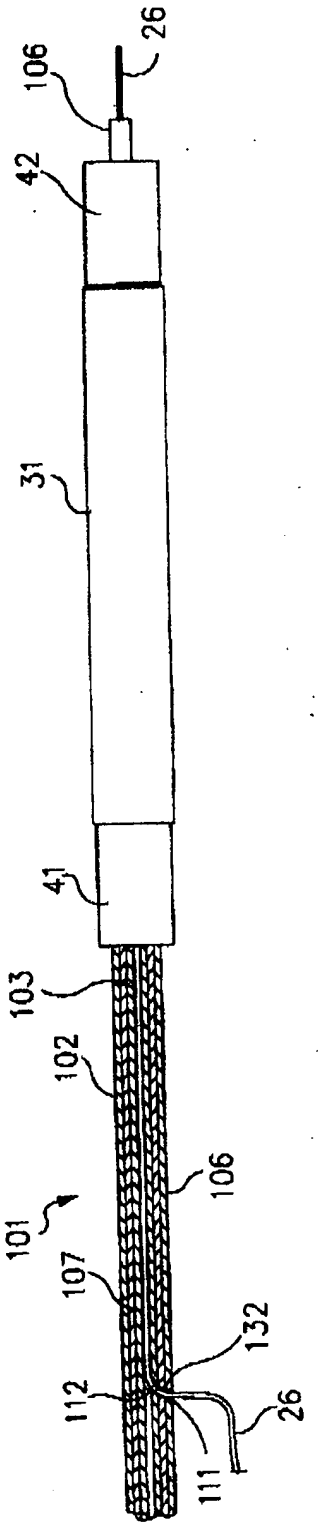


FIG.9

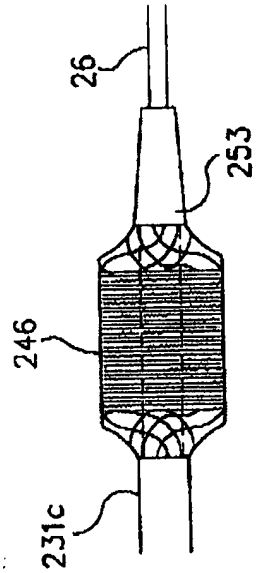


FIG. 10

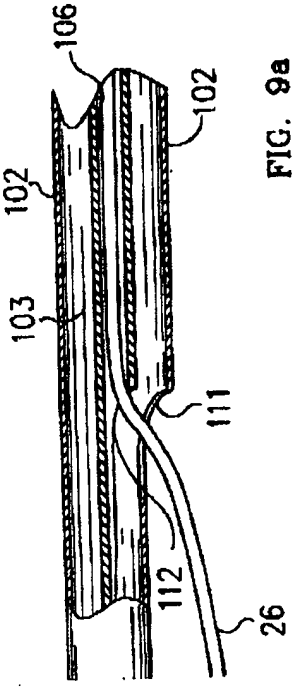


FIG. 9a

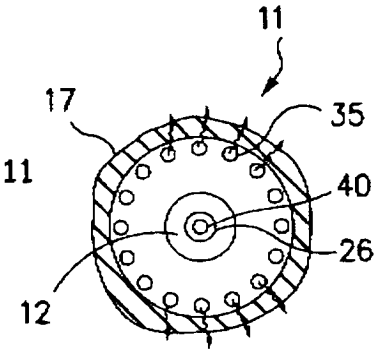


FIG. 11

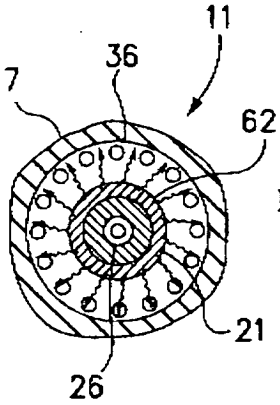


FIG. 12

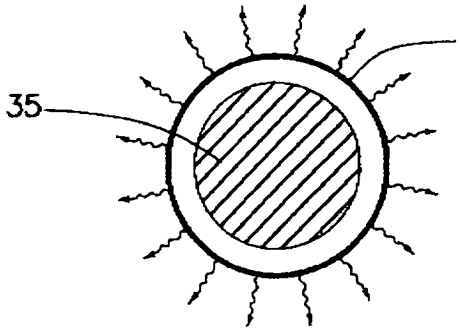


FIG. 13

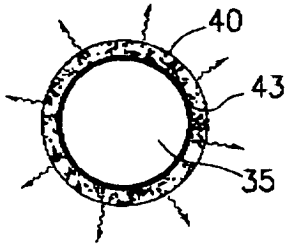


FIG. 14

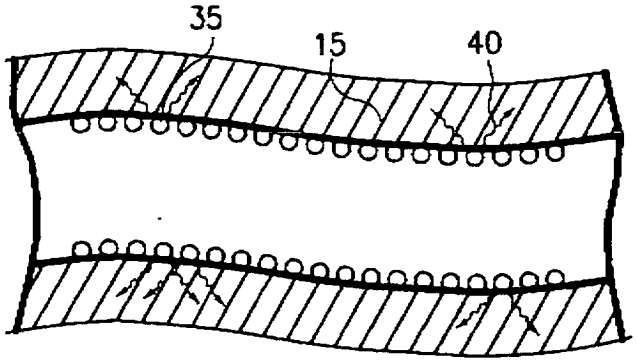


FIG. 16

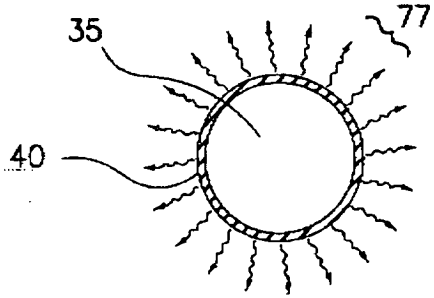


FIG. 15